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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,434	07/24/2003	Andrew Joseph Friedman	PRD-0007-US-CIP	9625

27777 7590 01/25/2006  
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EXAMINER

CHONG, YONG SOO

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/626,434	<b>Applicant(s)</b> FRIEDMAN ET AL.	
	<b>Examiner</b> Yong S. Chong	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/26/2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of the Application*

This Office Action is in response to applicant's remarks filed on 12/8/2005.

Claims 1-5 are pending. Election was made **without** traverse in the reply. The requirement is deemed proper and is therefore made FINAL. Claims 1-5 are examined herein.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/385,597. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims disclose an obvious variation of a method of contraception by administering to a menstruating female a composition

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comprising estrogen and progestogen for 42 consecutive days followed by a hormone-free period.

Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/955,276. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims disclose an obvious variation of a method of contraception by administering to a menstruating female a composition comprising ethinyl estradiol and norgestimate for 42 consecutive days followed by a hormone-free period. In both cases, the subtle differences in dosages and length of administration are obvious to one of ordinary skill in the art to optimize.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites "a hormone-free period following the 56 days of continuous therapy," however claim 2, from which it depends, recites 56 days or more. It is not clear whether claim 3 is meant to include all the limitations or further limit claim 2.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being obvious over Kovacs et al. (*The British Journal of Family Planning*, 1994, 19, pg. 274-275) in view of Smallwood et al. ("Efficacy and Safety of a Transdermal Contraceptive System" *Obstetrics & Gynecology*, vol. 98, no. 5, part 1, 2001, pg. 799-805).

The instant claims are directed to a method of contraception comprising administering to a menstruating female a transdermal composition comprising ethinyl estradiol and norelgestromin for at least 56 successive days.

Kovacs et al. teach a trimonthly method of contraception (pg. 274, left column, paragraph 1) for menstruating women (pg. 275, right column, paragraph 9). The contraceptive comprises a daily dosage of ethinyl estradiol (estrogen) and a progestogen (levonorgestrel) (pg. 274, right column, paragraph 3) for 12 weeks followed

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by one week of placebo (pg. 274, left column, paragraph 1). Half of the female patients discontinued the regimen because of breakthrough bleeding (pg. 274, left column, paragraph 1).

However, Kovacs et al. does not specifically disclose the combination of ethinyl estradiol and norelgestromin.

Smallwood et al. teach a method of contraception comprising administering a daily transdermal composition comprising ethinyl estradiol (20 µg) and norelgestromin (150 µg) for 21 consecutive days followed by 1-week hormone-free period. This method provides enhanced bleeding control and is well tolerated (abstract). The women must be sexually active and at risk of pregnancy as well as have regular menstrual cycles (pg. 800, right column, second paragraph).

It would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to substitute the contraceptive composition in the regimen as taught by Kovacs et al. with the composition comprising ethinyl estradiol and norelgestromin as taught by Smallwood et al.

A person of ordinary skill in the art would have been motivated to make this substitution because the composition disclosed by Smallwood et al. enhances bleeding control and is well tolerated in females.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
SHENGJUNWANG  
PRIMARY EXAMINER

YSC